NOV 19 2009

Edwards

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"510(k) Summary"

as required by section 807.92(c)

Summary: This summary was prepared on June 9th, 2009

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Device Trade Name: Aquarius system

Classification Name: High permeability hemodialysis system

Device Classification: The FDA has classified: 21 CFR 876.5860 High Permeability Hemodialysis System (78 KDI) as a Class II.

Common Name: Hemofiltration System

Predicate Device: Edwards Aquarius system
cleared under premarket notification K070320 on June 7, 2007

Brief Description: The general description of the device has not changed from the predicate version, K070320, except that the system has been validated to use specific legally market filter as opposed to a special Edwards Filter.

The Edwards Aquarius System needs to be used in conjunction with a tubing set and a filter to provide Hemofiltration treatment to the patient.

The tubing set has already been the subject of a PreMarket Notification, K063293 Edwards Aqualine Sterile Tubing Sets and suitable legally marketed filters have been identified.

The Aquarius system is an Automated Fluid Balance Monitor, designed to be used with various extracorporeal treatments in the field of renal replacement therapies or plasma therapies. All therapies must be prescribed by a physician.

The Aquarius system is divided into three circuits: the extracorporeal (blood) circuit, the substitution/dialysate circuit and the filtrate circuit.

Toxic substances are removed by filters and clean blood is returned to the patient.

The Aquarius system allows the patient to be positioned left or right of the instrument.

The Aquarius system uses two scales to accurately measure and precisely balance filtration and substitution volumes.

Heparin may be supplied to the extracorporeal circuit via an anticoagulant pump (Heparin pump). The prescribing physician may select continuous or intermittent options.

The Aquarius protective system is designed as a 2-channel system to protect the patient from foreseeable danger.
At the back of the scale system a removable hand-crank is mounted. This can be used to manually turn the blood pump in case a pump stops.

The Aquarius system is portable. It has a wheeled base connected with a handle to move or carry the Aquarius.

Intended Use: Continuous Renal Replacement Therapy:
SCUF, CVVH, CVVHD, CVVHDF
Plasma exchange (TPE)

Indications for Use: "The Aquarius System is indicated for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload. The Aquarius System may also be used in Therapeutic Plasma Exchange (TPE) therapies.

"The Aquarius System is indicated for use in a clinical setting and not for home use."

These are the **same indications for use** as the predicate Aquarius System cleared under K070320.

Substantial Equivalence: The Aquarius System is substantially equivalent to the predicate Aquarius System as follows:

- same intended use
- same indications for use
- same labels

- revised operating manual based on the draft labeling supplied in the predicate submission
- same operating principle
- same fundamental scientific technology with the exception of the algorithm improvements
- same hardware
- updated software (6.02.00) performing the same functions as the predicate software (version 6.00.04)
- same performance specifications
- same accessories
- continues to meet the safety requirements of UL and EMC standards

In summary, the Aquarius System is substantially equivalent to the predicate Aquarius System (K070320), with the same intended use and fundamental scientific technology.

Technological Characteristics:

Characteristic	Aquarius System K070320 (Predicate Device)	Modified Aquarius System (Proposed Device)
Weight	Approx. 75 Kg	Same as predicate.
Dimensions (H x W x D)	170 cm x 50 cm x 60 cm	No physical change, but quoted dimensions corrected in Operating Manual
Power Supply	115 v (a.c.) ± 10% at 60Hz (U.S.)	104 – 126 v at 47 – 63 Hz
Power Consumption	500 VA (theoretical value)	Maxium measured value 350w
Fluids Management	All parameters*, except: Heparin syringe size 30 ml or 50 ml	Same as predicate, except 50 ml only
Scales	All parameters*	Same as predicate.
Fluid Warmer	All parameters*	Same as predicate.
Pressure Monitoring	All parameters*	Same as predicate.
Degassing Unit	All parameters*	Same as predicate.
Monitor / Detection Parameters	All parameters*	Same as predicate.
Software Revision	6.00.04	6.02.00 (see above for description of differences between software revisions)

* refers to the parameters listed in the 510(k) summary for K070320
http://www.fda.gov/cdrh/pdf7/K070320.pdf

Performance Testing:

The submission is a special 510(k) for changes to software and labeling. No clinical or non-clinical data is presented, however a summary of design control activities and risk/hazard analysis for software changes is presented.

Conclusion:

The proposed modifications, included in this submission, update the software and labeling for the device. Edwards Lifesciences Services GmbH have demonstrated that these modifications do not alter the fundamental scientific technology or the intended use.

Edwards Lifesciences believes that these modifications are eligible for review through the Special 510(k) process and that the proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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c/o Mr. Neil R. Armstrong
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NOV 19 2009

Re: K090682
Trade/Device Name: Edwards' Aquarius system
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: October 13, 2009
Received: October 20, 2009

Dear Mr. Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090682

Device Name: Edwards' Aquarius system

Indications for Use:

The Edwards Aquarius System is indicated for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload. The Edwards Aquarius system may also be used in Therapeutic Plasma Exchange (TPE) therapies.

The Edwards Aquarius system is indicated for use in a clinical setting and not for home use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090682

(Posted November 13, 2003)